

Remarks

Claims 1 to 24 have been amended and new claim 25 has been added.

The amendment to claim 1 finds support in the specification of the corresponding PCT application at, *inter alia*, page 3, lines 21-22.

The amendment to claim 2 finds support in the specification of the corresponding PCT application at, *inter alia*, page 4, lines 16-17.

The amendments to claims 3, 10 and 11 find support in the specification of the corresponding PCT application at, *inter alia*, page 4, lines 18-19.

The amendment to claim 4 finds support in the specification of the corresponding PCT application at, *inter alia*, page 7, lines 1-8.

The amendment to claim 5 finds support in the specification of the corresponding PCT application at, *inter alia*, page 4, lines 20-21.

The amendments to claims 6, 7 and 8 find support in the specification of the corresponding PCT application at, *inter alia*, page 3, line 31 through page 4, line 1.

The amendment to claim 9 finds support in the specification of the corresponding PCT application at, *inter alia*, page 5, lines 13-14.

The amendments to claims 12 and 13 find support in the specification of the corresponding PCT application at, *inter alia*, page 8, line 33 through page 9, line 1.

The amendment to claim 14 finds support in the specification of the corresponding PCT application at, *inter alia*, page 9, line 14.

The amendment to claim 15 finds support in the specification of the corresponding PCT application at, *inter alia*, page 7, line 8.

The amendment to claim 16 finds support in the specification of the corresponding PCT application at, *inter alia*, page 9, lines 8-10.

The amendment to claim 17 finds support in the specification of the corresponding PCT application at, *inter alia*, page 8, lines 13-15.

The amendments to claims 18, 19 and 20 find support in the specification of the corresponding PCT application at, *inter alia*, page 2, lines 25-30.

The amendment to claim 21 finds support in the specification of the corresponding PCT application at, *inter alia*, page 22, lines 1-27.

The amendment to claim 22 finds support in the specification of the corresponding PCT application at, *inter alia*, page 2, line 32 through page 3, line 2.

The amendments to claims 23 and 24 find support in the specification of the corresponding PCT application at, *inter alia*, page 3, lines 2-6.

New claim 25 finds support in the specification of the corresponding PCT application at, *inter alia*, page 3, line 6.

Accordingly, Applicants submit that no prohibited new matter has been introduced by the amendments or the new claim.

1. Claim Objections

Claims 5 to 19, 23 and 24 are objected to as containing improper multiple dependency.

Applicants submit that as amended, none of the pending claims contain improper multiple dependency. Applicants therefore respectfully request that this objection be withdrawn.

2. Rejection under 35 U.S.C. 112, second paragraph

Claims 1 to 4 and 20 to 22 are rejected as allegedly indefinite for recitation of the phrase “wherein the process parameters are selected to give a product which demonstrates improved efficiency of filtration.” In addition, claim 4 is rejected as allegedly indefinite for recitation of the phrase “such that the addition time is selected to give a product which demonstrates improved efficiency of filtration.”

Without acquiescing to the merits of this rejection, Applicants have amended claims 1 and 4 to remove the contested phrases. Accordingly, Applicants respectfully request that this rejection be withdrawn.

3. **Rejection under 35 U.S.C. 102(b)**

A. Taylor

Claims 1 to 4 and 20 to 22 are rejected as allegedly anticipated by WO 01/60804 to Taylor *et al.* (“Taylor”). The Examiner cites Example 10 of Taylor as allegedly teaching Applicants’ claimed process.

Applicants point out that Example 10 of Taylor teaches the preparation of (E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidin-5-yl](3R,5S)-3,5-dihydroxyhept-6-enoic acid calcium salt by the dropwise addition of calcium chloride at 20°C (see page 14, line 30 of Taylor). There is no teaching or suggestion in Taylor of adding calcium chloride at any other temperature. As amended, Applicants’ claim 1 recites that a solution of calcium chloride is added to the water soluble salt at a temperature of 30 to 45°C. At least for this reason, Applicants respectfully request that this rejection be withdrawn.

In addition, a person of ordinary skill in the art would clearly not be motivated after reading Taylor to add the calcium chloride at a temperature of 30 to 45°C as recited in Applicants’ claim 1 as amended. As indicated in Applicants’ specification, Applicants have discovered that the process recited in claim 1 of the subject application unexpectedly results in a product that can be filtered more efficiently to remove undesired solvents, compared to previously reported preparations of the product (see, *e.g.*, page 2, lines 6-8). A person of ordinary skill in the art would appreciate that “a product which is isolated with a low solvent (such as water) content requires less drying time after isolation than one with a higher solvent content in order to achieve the same overall endpoint” (page 2, lines 11-13).

B. Bryant

Claims 1 to 4 and 20 to 22 are rejected as allegedly anticipated by WO 00/49014 to Bryant *et al.* (“Bryant”). The Examiner cites Example 7 of Bryant as allegedly teaching Applicants’ claimed process.

Applicants point out that Example 7 of Bryant also teaches the preparation of (E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidin-5-yl](3R,5S)-3,5-dihydroxyhept-6-enoic acid calcium salt by the dropwise addition of calcium chloride at 20°C

(see page 10, lines 1-6 of Bryant). There is no teaching or suggestion in Bryant of adding calcium chloride at any other temperature. As amended, Applicants' claim 1 recites that a solution of calcium chloride is added to the water soluble salt at a temperature of 30 to 45°C. At least for this reason, Applicants respectfully request that this rejection be withdrawn.

In addition, a person of ordinary skill in the art would clearly not be motivated after reading Bryant to add the calcium chloride at a temperature of 30 to 45°C as recited in Applicants' claim 1 as amended.


4. Conclusion

The foregoing amendments and remarks are being made to place the application in a condition for allowance. Applicants respectfully request reconsideration and the timely allowance of the pending claims. Should the Examiner find that an interview would be helpful to further prosecution of this application, he is invited to telephone the undersigned at his convenience.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or to credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **Constructive Petition for Extension of Time** in accordance with 37 C.F.R. 1.136(a)(3).

Dated: **April 3, 2008**
Morgan, Lewis & Bockius LLP
Customer No. **09629**
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
Tel: 202-739-3000
Fax: 202-739-3001

Respectfully submitted
Morgan, Lewis & Bockius LLP



Gregory T. Lowen
Registration No. 46,882
Direct: 202-739-5915